UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE IN RESEARCH

Study Title:	Assessing the Safety of Pregnancy In the CoRonavirus pandEmic: A Nationwide Prospective study (ASPIRE)
Principal Investigator:	Heather Huddleston, MD, Professor Obstetrics, Gynecology and Reproductive Sciences University of California, San Francisco 550 16th Street, 7th Floor, San Francisco, CA 94158 415.353.3040 Heather.Huddleston@ucsf.edu

This is a medical research study, and you do not have to take part. The researchers, Heather Huddleston, M.D., Eleni Jaswa, M.D., M.Sc., and Marcelle Cedars, M.D. from the University of California San Francisco Department of Obstetrics, Gynecology and Reproductive Sciences, Center for Reproductive, will explain this research to you. If you have any questions, you may ask the study doctor.

You are being asked to take part in this study because you conceived naturally or with assistance (ovulation induction, intra-uterine insemination and IVF) beginning December 2019 through December 2020.

In this study, the researchers are collecting blood samples and asking you to complete questionnaires in order to learn more about maternal and fetal effects of early pregnancy infection with SARS-CoV-2.

Why is this study being done?
This study is being done to help better understand how COVID-19 impacts pregnant women and their newborns. There are currently no data available about the effects of COVID-19 on pregnancies when infection occurs in the first trimester. This study aims to help provide this critical information to better understand risks and precautions that might promote pregnancy safety.

What will happen if I take part in this study?

If you agree to be in this study, you will be followed throughout your pregnancy and may be asked to:

1. Complete a study questionnaire at the time of enrollment. It will include questions detailing sociodemographic background, medical and surgical history, obstetric history, medication use, and health behaviors.
2. Provide frequent updates about COVID-related symptoms during pregnancy on your mobile phone.

3. Provide blood samples on a blood spot card (3-5 drops of blood from a finger prick) at several time points throughout your pregnancy to test for infection. Participants will be mailed a kit containing blood spot cards, all necessary materials (lancets and alcohol swabs) and detailed instructions regarding cleansing/preparing the finger and finger stick procedure. The study will provide return mail envelopes for participants to return blood spot cards at the end of every trimester.
4. Complete follow-up study questionnaires once per trimester and at 6 weeks, 6 months, and 1 year after delivery.
5. Allow us to review your medical records in order to gather general medical and obstetrical history related to your pregnancy and delivery.

Are there risks?

The finger prick may hurt. There is a small risk of bruising and a very rare risk of infection. You may experience discomfort related to filling out certain questions regarding your medical history. You may skip any questions you feel uncomfortable answering.

Are there benefits?

There is no direct benefit to you. However, the information you provide may help patients, providers, and women who plan to conceive better understand critical information regarding maternal and fetal implications of early pregnancy infection or exposure to SARS-CoV-2.

Can I say "No"?

Yes. You do not have to donate a blood sample or complete questionnaires for this study. You can decide to stop your participation at any time. If you decide later that you do not want your samples and information to be used for future research, you can notify the Primary Investigator in writing at the address on the front page and we will destroy any remaining identifiable banked samples and associated information. However, if any research has already been done using portions of your specimens, the information will be kept and analyzed as part of those research studies. Your decision to stop being in the study will not affect your regular benefits or ongoing or future medical care at UCSF.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

Will my medical information be kept confidential?

We will do our best to protect the information we collect from you and your medical record. Information that identifies you will be kept secure and restricted. If information from this research is published or presented at scientific meetings, your name and other identifiers will not be used. Information that identifies you will be destroyed when this research is complete. The following organizations may look at de-identified information about you in the research records:

- The University of California

- Collaborating researchers from SART (Society for Assisted Reproductive Technology)

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Are there any costs or payments?

You will not be paid for taking part in this study. No additional costs will be incurred by your participation in this study.

What if I get injured?

Tell the study doctors, Drs. Heather Huddleston, Eleni Jaswa, or Marcelle Cedars if you feel that you have been injured because of being in this research. You can tell the doctor in person or call him/her at 415-353-7475.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

Who can answer my questions about the study?

You can talk to the study doctors or study coordinators about any questions, concerns, or complaints you have about this study. Contact the study doctor(s), Drs. Heather Huddleston, Eleni Jaswa, or Marcelle Cedars in person or call him/her at 415-353-7475.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

If you wish to be in this study, please sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent

Preffered mailing address:

Name/ATTN: _____

Delivery Address: _____

City, State, ZIP Code: _____